105B-0186

正本

檔　　號：
保存年限：

新北市政府衛生局　函

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24158
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受文者：新北市藥師公會

發文日期：中華民國105年3月14日
發文字號：新北衛食字第1050381254號
速別：普通件
密等及解密條件或保密期限：
附件：仿冒藥品訊息相關資料1份

主旨：檢送案內藥品「Dysport(批號A00703及F05302）」之仿冒品於境外流通相關資料，為維護國民之健康與安全，請轉知所屬會員勿販售供應與使用，請查照。

說明：

一、依據衛生福利部食品藥物管理署105年3月3日FDA企字第1051200765號函辦理。

二、檢附仿冒藥品訊息相關資料1份。

正本：新北市藥師公會、新北市藥劑生公會、新北市醫師公會、新北市西藥商業同業公會、新北市商業會
副本：新北市政府衛生局衛生稽查科

局長 林奇宏

本案依分層負責規定授權業務主管決行

RAPID ALERT NOTIFICATION OF A QUALITY DEFECT/RECALL		
IMPORTANT - DELIVER IMMEDIATELY		Ref. IT/I/2/01
1.To: (see list attached, if more than one)		
2.Product Recall Class of Defect: I	**3.Counterfeit / Fraud (specify)*:** Counterfeit	
4.Product: Dysport	**5.Marketing Authorisation Number:*** For use in Humans/ ~~animal~~	
6.Brand/Trade Name: Dysport	**7.INN or Generic Name:** botulinum toxin	
8. Dosage Form: powder for solution for injection	**9. Strength:** 500 UI	
10.Batch/Lot Number: A00703; F05302	**11.Expiry Date:** 02/2017 11/2016	
12. Pack size and Presentation: vials without secondary packaging	**13. Date Manufactured:**	
14. Marketing Authorisation Holder:	Ipsen S.p.A.	
15. Manufacturer: **Contact point:**	**16. Recalling Firm (if different):**	
17. Recall Number Assigned (if available): Ref. IT/I/2/01		
18. Details of Defect/Reason for Recall: An Italian physician has found during his activity some vials of the medicine Dysport 500 UI (API botulinum toxin), batch A00703 expiry date 02/2017 and batch F05302 expiry date 11/2016, showing quality defects related the closure (the vials were not easy to open due to the strong adherence of the aluminum cap to the glass). The vials showed also leakage of the powder. The Marketing Authorization Holder (IPSEN S.p.a.) declared that the batch numbers were fake and didn't match with the genuine ones.		
19.Information on distribution including exports (type of customer, e.g. hospitals):		
20. Action taken by Issuing Authority: communication to the general public through the official website and to the Health professionals organizations (healthcare professionals)		
21.Proposed Action:		
22.From (Issuing Authority): AIFA – Product Quality and Counterfeiting Office	**23.Contact Person:** Domenico Di Giorgio, Ph D. d.digiorgio@aifa.gov.it medicrime@aifa.gov.it	
24.Signed: Domenico Di Giorgio	**25.Date:** 24 February 2016	**26.Time:***

COUNTERFEIT DYSPORT 500 UI – batch A00703 exp. 02/2017